Validity of Electronic Prescription Claims Records: A Comparison of Commercial Insurance Claims with Pharmacy Provider Derived Records

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Key Words: Prescription Claims, Pharmacy Records, Retrospective, Validity, Reliability

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Take Home Messages:

- PBM prescription claims data are often implictly assumed to be complete
- PBM data are used to measure exposure to prescription drugs in many observational studies
- 93% of PBM derived pharmacy claim records were source verified with pharmacy provider records
- PBM benefit features were not consistently related to persons with missing PBM records
- There was wide variability between therapeutic classes with regard to missing PBM records

Abstract
Objectives: *To determine if and to what extent records obtained from PBM pharmacy claims differ from source documents obtained directly from pharmacy providers. This study also sought to explore possible associations between patient, pharmacy benefits, and pharmacy provider characteristics and the likelihood a patient would have missing prescription claims.*
Methods: *This study used a cross-sectional design which included a sample of 1,484 patients residing in a single state with a common pharmacy benefit. Profiles describing all prescriptions filled in a pharmacy between January 1, 2002 through June 30, 2002 of these patients were requested directly from their pharmacy providers. Logistic regression was used to explore the factors associated with a person receiving a prescription that did not appear on the PBM claims.*
Results: *Of the 1,484 eligible recipients sampled, profiles were obtained for 323 (22%) persons and there were analyzable profiles for 315 (21%) persons. There were a total of 2,977 prescriptions filled for the 315 subjects. Of those 2,977 prescriptions, 207 (7.0%) were missing from the claims files indicating that 93% were captured. Only prescription volume consistently influenced the likelihood a patient would have a missing prescription from the PBM claims (OR =1.08; 95%CI:1.05-1.12).*
Conclusion: *Claims obtained from pharmacy benefit companies capture approximately 93% of prescription records when verified with records obtained from pharmacy providers. The rate of missing records from PBM claims does not appear to be meaningfully influenced by most finance based pharmacy benefit design features. However, certain classes of drugs such as iron products, digoxins, diuretics, sulfonylureas, and antigout may have incomplete claims records compared to other classes of drugs. Higher prescription utilizers are more likely to have prescription records filled that are not captured by PBMs. These conclusions should be interpreted in light of the modest usable response rate from pharmacy providers of 22% and the unknown generalizability of these patients utilizing one particular PBM from 2002 in the state of Georgia.*

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Introduction

Electronic health claims databases are increasingly being utilized to conduct a wide range of epidemiologic, safety, economic, and health policy investigations. Prescription claims records are a key component to many of these types of observational studies. In epidemiologic and safety investigations, prescription claims are often used as the sole measure of 'exposure' to determine both the presence or absence of drug exposure as well as the intensity of exposure (dosage, duration, quantity). In economic and health policy investigations, prescription drug claims are used to define treatment groups for cost comparison and outcomes studies and they are an important component of the total health care costs.[1-6] Prescription claims database have also been used as a standard to compared the validity of other drug exposure sources such as self-reported drug use, however, the sources to assess drug exposure have potential for inaccuracies.[7, 8]

Prescription claims records are the electronic artifacts documenting the financial transactions between patients, pharmacy providers and health care payers. The electronic records generated from these transactions typically include patient, drug, and payment information that can be used alone or linked by patient identifier with other medical claims or clinical information systems for research purposes.[9] In the U.S., pharmaceutical benefit managment companies (PBMs) serve as the fiscal intermediary between pharmacy provider and health payers and the ten largest PBMs provided benefits for over 700 million persons in the U.S. in 2011.[10, 11] Because of their sheer size, the electronic prescription claims data derived from PBMs are one of the most common sources of prescription drug information used for retrospective pharmacoepidemiologic research.[12]

Prescription claims files are frequently used for research purposes and the accuracy of these prescription claims to measure cost or exposure is largely unknown. Despite the financial incentives for pharmacists to submit prescription claims to a PBM, there are many reasons why this may not occur thus circumventing the capture of the electronic prescription record. Some of those reasons might be: the drug may cost less than the amount of a copay, the prescription may be for a non-covered item or requires prior authorization, the persons may want to protect their confidentiality, persons may have exceeded a cap or maximum limit, or persons may be enrolled in two or more insurance plans. When prescription claims records are not complete, there is a fundamental measurement bias which may result in case ascertainment bias, exposure misclassification biases, or systematic underestimation of prescription utilization and costs. [12-14]

To date, there is little evidence empirically testing this assumption. There have been indirect assessments of accuracy of prescription claims by comparing drug compliance measures using pharmacy claims data with other compliance measures including patient self-reported measures[15, 16] and studies testing the accuracy of prescription claims information to define or supplement case definitions for hypertension.[17] Direct assessments of the validity of prescription claims comparing prescription claims with other medical data, such as a patients chart, have generally been performed in narrow populations or for selected drug classes and the results have been highly variable.[8, 13, 18-23]

Another approach to assess the accuracy of prescription claims files would be to compare the prescription claims records with pharmacy provider profiles. This approach has decided advantages over comparisons with medical charts and patient information since pharmacy records are maintained in electronic and paper forms. Also, the pharmacy profiles represent medications that were picked up at the pharmacy rather than those for which a prescription was written which may or may not have ever been filled. Furthermore, the pharmacy records of pharmacy providers have been found to be a reliable source to determine the drug exposure when compared to patient self report.[24-26] There have been two U.S. Medicaid based studies and one Canadian study comparing prescription records to electronic claims files.[3, 27, 28] However, two of these studies were conducted in government payer systems which provide benefits to the poorest patients and we do not know the accuracy of these claims for commercial populations,[3, 27] and the other focused on prescriptions that were abandoned or refilled but did not validate the PBM records.[29]

The overarching goal of this study was to address this information gap by assessing the validity of electronic prescription claims records for persons with commercial pharmacy benefits in the U.S. More specifically, the objective of this study is to determine if and to what extent records obtained from PBM pharmacy claims differ from source documents obtained directly from pharmacy providers. Also, this study sought to explore possible associations between patient characteristics (gender, age), pharmacy benefit characteristics (copay amount, 2 / 3 tier copay structure, deductible, coinsurance), or pharmacy provider characteristics (chain / independent) which influences the likelihood a patient would have missing prescription claims from the PBM electronic prescription claims records.

Methods

Study Design

This study used a cross-sectional study design. The general framework was to sample patients residing in a single state with a common pharmacy benefit from one of the nation's largest PBMs, Express Scripts Inc., and survey their pharmacy providers and request that they return patient profiles (record of all prescriptions dispensed) for those persons with patient identifiers removed. Prescription records obtained from the pharmacy providers were then linked by encrypted patient identifier to the prescription records obtained from the PBM and compared.

Sample and Data Collection

Recipients were identified by searching the PBM's recipient data of over 44,000 commercial persons eligible for pharmacy benefits in Georgia. The following inclusion and exclusion criteria were applied to identify eligible recipients:

1. Continuously eligible for pharmacy benefits from January 1, 2002 through June 30, 2002.
2. At least 18 years of age on January 1, 2002
3. Had pharmacy claims from no more than one pharmacy store during the study period.
4. Resided and utilized pharmacies in Georgia.
5. Had a rider in their pharmacy benefit contract that permitted the PBM to conduct research using their pharmacy data.
6. Exclude members with HIV or antipsychotic prescription claims
7. Exclude persons with mail order claims
8. Exclude persons with member submitted claims

These criteria were utilized to minimize the chances of persons utilizing pharmacies not sampled and to exclude patients that may have obtained their prescriptions from charity or public health clinics (HIV and antipsychotic users). After applying the inclusion and exclusion criteria, 21,303 subjects were eligible to participate. From the eligible pool of recipients, subjects were randomly chosen within plan features (3-tier copay, 2-tier copay, coinsurance, and deductibles) so that those with less common prescription plan features (coinsurance and deductible) would be adequately represented. Due to budgetary considerations and the sampling scheme to identify recipients with all plan features, 1,771 subjects were randomly selected. Each subject's pharmacy provider was identified, and each pharmacy was mailed a letter requesting prescription profiles to be returned for the subjects identified in the sample that utilized their pharmacy. There were 818 pharmacies in the initial sample that provided pharmacy services for the 1,771 selected subjects. The letter contained instructions requesting the pharmacist to return pharmacy profiles containing all prescriptions filled during the study period from January 1, 2002 through June 30, 2002 in a pre-paid postage envelope. The patient profiles requested were typical print outs that patients routinely ask their pharmacists to prepare for them for tax and/or insurance purposes. Pharmacists were provided with the recipient name and date of birth, so that they could identify the sample persons. The pharmacists were then instructed to de-identify the prescription records and to place an encrypted identifier on the prescription profile so that the records could be later linked to the PBM claims data. The pharmacy letter was initially mailed out on December 2002, and there was a follow-up reminder post card mailed approximately 6 weeks after the initial mailing. All the patient prescription records were entered into a relational database by trained, blinded data entry personnel who had retail pharmacy experience. The data entry personnel were blinded in the sense that they had no access to the PBM claims information and could not be influenced by those records when keying records from the pharmacy profiles. Key fields (encrypted ids, NDC numbers and dates or prescription fill) were double keyed entered. After the pharmacy profile records were linked to the PBM records by encrypted ID, date, and NDC number, those keyed records that were discordant were identified and verified with source documentation. Initially there were 542 discordant prescription records. Corrections to the pharmacy profile data were made by inspecting the source records and keying errors were fixed. Also, NDC codes were set to match claims file for 79 profile records when the same drug was dispensed on the same day for the same patients as indicated from the claims, but had an NDC code that did not match the claims. For example, drugs subject to MAC (Maximum Allowable Costs) pricing may have different NDC codes on the claims file for multi-source products such as acetaminophen and hydrocodone.

All prescriptions were merged with Multum therapeutic classifications (http://www.multum.com) and supplemented with a PBM supplied therapeutic classification for prescription NDCs that could not be matched with Multum therapeutic classes. Those records that did not appear in the PBM claims files (prescriptions exclusively from pharmacy profiles) were merged with a file supplied by the PBM describing the Drug Utilization Review (DUR) edits and rejects which provide some details on why a claim was not reimbursed by the PBM.

To account for the oversampling of persons with certain pharmacy design features, sample weights were derived from the posterior probabilities of being selected into the sample.

For example, all 272 (100%) persons in the eligible population that had a coinsurance were selected into the sample. However, only 5.9% of the eligible population that had a two-tier benefit were selected into the sample. Consequently, persons with coinsurance were relatively oversampled and consequently were assigned a lower sampling weight. The analysis reports the unweighted results as the base case and the weighted results are presented when relevant.

This study was approved by the Institutional Review Board (IRB) of the University of Georgia Humans Subject Office.

Analysis

The weighted and unweighted number of prescriptions by source (Profile only, PBM only, both) was calculated. The denominator for all calculations was unduplicated prescription records irrespective of source (records from both the PBM claims and Profiles were only counted as one). The sensitivity and positive predictive value (PPV) of the prescription record as a unit of analysis was calculated utilizing the pharmacy profile records as a 'gold-standard' measure. For each analyzable subject, a patient level file was constructed denoting the number of prescriptions filled from each source of information. Utilizing the patient level file, an exploratory analysis sought to identify associations between patient demographic and pharmacy benefit features and the likelihood of obtaining one or more prescriptions that were not adjudicated with the PBM. The variables available guided the comparisons and specifically the following variables were explored a-priori: age, percent elderly (age > 65 years), gender, pharmacy type (Independent vs. Chain), number of Rxs, sum paid for all Rxs, presence of a deductible, family deductible amount, member deductible amount, presence of coinsurance, presence of a three-tier copay, generic copay amount, preferred brand copay amount, non-preferred brand copay amount. Univariate associations were explored using t-test, approximate t-test with a Satterthwaite correction (when variances were not equal), and Chi-square tests. Logistic regression using the maximum likelihood method was used to obtain adjusted odds ratios of receiving prescriptions not adjudicated with the PBM. To explore some plan features, such as the level of copay across tiers, the analysis required the subject to be in a tiered plan and not all subjects could be included in those analyses which resulted in several model specifications to assess each of the plan features.

Results

A total of 189 pharmacies (23%) responded to the request to obtain prescription profiles. Of those, 6 provided unusable patient profiles (no dates supplied by one, and three did not return encrypted identifiers, one refusal, and one pharmacy could not confirm the date of birth) bringing the usable response rate to 183 (22%). These 183 pharmacies provided profile information for 363 recipients which represented 20% of the original 1,771 sampled recipients.

During the course of the study, it was determined that one health plan whose recipients were initially part of the sample did not want their members to be included in the study. This health plan had 287 members initially included in the sample. After applying this post-hoc exclusion, the initial sample was reduced to 1,484 eligible recipients, and the number of recipients with a profile decreased to 323 (22%).

Table 1 contains the demographic statistics of the 1,484 eligible recipients that were surveyed and the 323 with profiles returned. The average age of the sample was about 46 years and approximately 60% were female. There were no statistically significant differences between recipients with a pharmacy profile and those without pharmacy profiles on any of the pharmacy benefit features (p>0.05) or demographic characteristics.

There were a total of 3,112 prescription records, 3,000 originated from the pharmacy profiles and 2,880 came from the PBM claims for these 323 persons. Out of 323 persons, there were 4 persons who had valid pharmacy profiles returned without any prescription records but had prescription records on the PBM claims. There were also an additional 4 recipients who had no prescriptions match on either profile (100% of prescription records were discordant). In both of these circumstances, it appears that despite the source verification for these pharmacy profile records, there may have been profiles returned for the wrong person or there may be errors with the encrypted IDs supplied by the PBM. A post-hoc decision was made to exclude these subjects from further analysis resulting in a final sample of 315 subjects for which there is valid prescription information from both the pharmacy profiles and the PBM claims (Figure 1).

For the final analyzable sample of 315 subjects, there were a total of 2,977 prescriptions (9.45 Rxs per person; 1.6 Rxs per person per month) filled. There were only 16 (0.5%) prescriptions records that appeared on the PBM claims without a corresponding record on the pharmacy profiles (Figure 1). An overwhelming majority (n=2754, 92.5%) of prescription records appeared on both the pharmacy and PBM prescription sources with the remaining 207 (7.0%) that appeared only on the pharmacy profiles corresponding to a PPV=99.42% and sensitivity=93.01%. When the sampling weights were used to adjust for the non-random sampling procedure, 6.5% of all prescriptions appeared only on the pharmacy profiles that were missing from the PBM claims and 0.4% of all prescriptions appeared on the PBM claims that were not included on the pharmacy profiles.

The therapeutic classes of the prescriptions that had 5 or more prescriptions missing from the PBM claims (identified only through the profiles) and the most common therapeutic classes are displayed in Figure 2. Hormones and drugs that can be used to treat cardiac conditions and hypertension were the most common drugs used by this sample. Prescriptions for iron products, inotropics, antigout, loop diuretics, and sulfonylureas, were most likely to be missing from the PBM claims as 75%, 67%, 42%, 29.4%, and 20% of the prescriptions for these therapeutic classes, respectively, were not recorded on the PBM claims.

There were 61 persons (19.4%) that had one or more prescriptions that were not contained on the PBM prescription records. When sampling weights were used, 18.2% of persons had one or more prescriptions that were not contained on the PBM prescription records. A majority (54.1%) of those persons had just a single prescription that was not contained on the PBM claims records (Table 2). Only 9 (2.9%) persons had, on average, more than one prescription per month (6 in the 6 month study period) filled that was not captured on the PBM claims. The source of payment for the prescription records captured exclusively from the pharmacy profiles was recorded where possible. For 77 of the profile derived prescription records, the pharmacy profiles were not detailed enough to determine the source of payment for these records. For the remaining 130 pharmacy profile derived records, there were 97 (74.6%) prescriptions that were paid for out of pocket and 33 (25.4%) prescriptions that were paid for by a third party other than the PBM (Table 2).

Persons who had missing records from their PBM claims files consumed more prescriptions in total and paid more for prescriptions over the 6 month period than did persons with all their prescriptions contained on the ESI claims (Table 3: $p<0.0001$). When sampling weights were used, the same associations between prescription volume and total prescription price were found between persons with missing records from the PBM claims (Table 3: $p<0.05$). Both the weighted and unweighted multivariate results confirmed the positive relationship between the total prescription volume and the likelihood of having a prescription filled without a claim appearing on the ESI prescription records (Table 4). In the unweighted analysis, a one dollar increase in the generic copay amount was associated with a 12% increase in odds of having at least one prescription not submitted to the PBM. However, this relationship was not significant in the weighted analysis. Similar results were obtained with the alternate model specifications where those with three tier, two tier, deductible and coinsurances were dichotomized including the entire sample.

The average amount paid by the patients tended to be higher for prescriptions not reimbursed than those prescriptions adjudicated with the PBM; but were not significantly different unless 2 prescriptions with paid amount > $1,000 were excluded ($23.21 vs. $15.92 $p=0.0003$). The days supply tended to be higher for prescriptions not adjudicated with ESI, but the increase of approximately 2 days supply was not significant. There were only 7 prescriptions not adjudicated with PBM that had days supply > 31 days.

The DUR edits file identified reasons for 72 prescription records that were filled in the pharmacy but not paid for by the PBM. The three most common reasons were: product / service not covered, followed by refill too soon, and refills not covered. These three reasons accounted for over 80% of the reasons for claim rejects.

Discussion

This study determined that the two sources of prescription information had fairly good agreement as over 90% of records from both sources were captured on both the PBM claims and the pharmacy profiles which is reflected in very high sensitivities and positive predictive values over 90%. There are very few occurrences (< 1%) of prescription records on the PBM claims that do not appear on the pharmacy profiles. However, there is a modest (7%) number of prescriptions found only on the pharmacy profiles and not on the PBM claims. These results are similar to other previous findings. A study comparing medical records, pharmacy records, and Medicaid prescription claims records for 37 Medicaid eligible persons found that 93% and 83% of the Medicaid prescription records were accurate relative to the pharmacy files and medical records respectively.[27] Another Canadian study comparing Drug Programs Information Network in Manitoba found that the accuracy of the claims ranged from 80% to 90% depending on the eligibility status of the person.[28] If one were to use a stricter standard where the person is the unit of analysis, nearly 20% of persons had one or more prescriptions that did not appear on the PBM claims, though a majority of these persons had just a single prescription not adjudicated with the PBM over the 6 month time horizon.

Unfortunately, there was just one consistent predictor, prescription volume, which was more likely to result in prescriptions not adjudicated with PBM. Patients utilizing more prescriptions may be just more likely to have missing plan information than patients with lower volume of prescription, simply due to the fact that they have more records that could be missing. This is corroborated by a study of 743 high Medicaid prescription users that found that the Medicaid prescription claims were missing for 21% of the prescription records obtained directly from pharmacy providers.[30] The amount of the drug copays and the pharmacy type were inconsistent or non-significant predictors. This would suggest that not having a prescription claim adjudicated is more or less at random with regard to plan and patient characteristics after accounting for the number of prescriptions filled.

Despite the overall high rate of concordance between the claims and pharmacy profiles, there were several categories of drugs with much lower rates of concordance such as specialty (uncategorized) prescriptions, OTC Iron products, and inotropics (digoxin) in which the PBM claims were missing for over 50% of those prescription records. Prescriptions for less expensive generic drugs such as diuretics, sulfonylureas, and antigout agents were also missing from the PBM claims 20-50% of the time. The implications of this finding are that despite the relative completeness of the electronic claims files overall, using only the electronic claims may substantially underestimate exposure to certain classes of drugs, particularly those that are inexpensive or not covered on the formulary. Unfortunately, the sample sizes of any one therapeutic category in this study with the lower concordance rates noted is relatively small (n<50) so these results should be interpreted with caution.

For an appreciable number of persons with missing prescriptions records from the ESI claims, access to multiple PBMs which may be obtained through a spouse or parent and depending on the benefit structure of the PBM plans occurred for at least 18% of the 61 persons with missing prescription claims from the PMB. This is a conservative estimate because the source of payment could not be obtained from the pharmacy profiles for 77 of the non-ESI prescription records. Another reason to not submit the claims to the PBM may be to obtain a greater days supply which may be cost saving as well as time saving for the patient. The data in this study do not suggest that this is a meaningful concern as only 7 prescriptions out of the 206 prescriptions had a day's supply greater than 31 days which is a typical limit for many PBM beneficiaries at retail settings.

Limitations

There were 8 patients that had valid pharmacy profiles returned that were excluded post-hoc because they had either no pharmacy records on their profile or had absolutely no overlap between prescription records the ESI and pharmacy profiles. It is believed that the pharmacy may have returned the wrong profile for these patients or there may have been some other administrative errors where the correct patient could not be linked to the original PBM claims. We recognize that by excluding these persons, the rate of prescription concordance is higher than would be estimated if the records were retained. A response rate of 22% is modest, and it is possible that pharmacy profiles obtained from pharmacy providers who responded to the survey may not be representative of the whole. As a check for potential response bias, the demographic and pharmacy provider characteristics were checked against the whole sample and no significant differences were detected, though those with deductibles trended towards higher response rates. Also, the sample was not selected completely at random from all PBM beneficiaries. A weighting scheme was used to attenuate the non-random sampling and the weighted results are reported where relevant and had little impact on the findings in most cases. It should also be noted that patients without any PBM claims were not sampled because there was no practical way to identify their pharmacy provider and this restriction prevented the calculation of other measures of accuracy including specificity and negative predictive values. The pharmacy profiles were considered as a gold standard which was necessary to calculate sensitivity and positive predictive value, but we recognize that all widely used methods to assess drug exposure, including pharmacy profiles, may misclassify true exposure status. To protect the patient confidentiality and minimize the effort of pharmacists who voluntarily participated in this study, no additional patient data was sought. This meant that possible factors, such as race, could not be explored in this study. There are no standards for the format or even the minimum content for the information supplied on pharmacy profiles. The variability in the pharmacy profiles and the lack of various fields in some profiles made it impossible to collect uniform prescription information for all prescription records. This is most recognizable when the source of payment is missing for 77 of the 207 records derived exclusively from the pharmacy profiles. Some pharmacy benefit characteristics such as the coinsurance amounts, deductible amounts, or copay amounts, could only be assessed in subsets of the entire sample (i.e. those with coinsurance or a deductible) which in some cases reduced the sample size for those analyses. Since the study used data from 2002, the accuracy of more contemporary commercial PBM claims may be different particularly given the growth of electronic prescribing and $4 generic programs and the implementation of Medicare Part-D benefits. Lastly, the estimates obtained from this study are from a single PBM for recipients in a single state. To the extent the pharmacy benefit designs and population characteristics between this population and others differ and influence the estimates obtained herein, our results are limited in their generalizability.

Conclusions

Claims obtained from pharmacy benefit companies capture approximately 93% of prescription records when verified with records obtained from pharmacy providers. The rate of missing records from PBM claims sources does not appear to be meaningfully influenced by most pharmacy benefit design features such as deductibles, coinsurance, copays, or tiered plans nor most patient characteristics. Higher prescription utilizers are more likely to have prescription records filled that are not captured by PBMs than their lower prescription utilizing counterparts. Electronic prescription records may be less complete for less expensive generic products and OTC products.

References

1. Gram LE, Hallas J, Andersen M. Pharmacovigilance based on prescription databases. *Pharmacol Toxicol*. 2000;86 Suppl 1:13-15.
2. Mahadevan U, Loftus EV,Jr, Tremaine WJ, Sandborn WJ. Safety of selective cyclooxygenase-2 inhibitors in inflammatory bowel disease. *Am J Gastroenterol*. 2002;97(4):910-914. doi: 10.1111/j.1572-0241.2002.05608.x.
3. Martin BC, Ganguly R, Pannicker S, Frech F, Barghout V. Utilization patterns and net direct medical cost to medicaid of irritable bowel syndrome. *Curr Med Res Opin*. 2003;19(8):771-780. doi: 10.1185/030079903125002540.
4. Motheral B, Fairman KA. Effect of a three-tier prescription copay on pharmaceutical and other medical utilization. *Med Care*. 2001;39(12):1293-1304.
5. Smalley W, Ray WA, Daugherty J, Griffin MR. Use of nonsteroidal anti-inflammatory drugs and incidence of colorectal cancer: A population-based study. *Arch Intern Med*. 1999;159(2):161-166.
6. Tseng CW, Brook RH, Keeler E, Mangione CM. Impact of an annual dollar limit or "cap" on prescription drug benefits for medicare patients. *JAMA*. 2003;290(2):222-227. doi: 10.1001/jama.290.2.222.
7. Allin S, Bayoumi AM, Law MR, Laporte A. Comparability of self-reported medication use and pharmacy claims data. *Health Rep*. 2013;24(1):3-9. doi: 82-003-X201300111764 [pii].
8. Kwon A, Bungay KM, Pei Y, et al. Antidepressant use: Concordance between self-report and claims records. *Med Care*. 2003;41(3):368-374. doi: 10.1097/01.MLR.0000053019.79054.B6.
9. Charlotte Seckman. Electronic health records and applications for managing patient care. In: Elsevier and typesetter Toppan Bes; 2013:87.
10. PricewaterhouseCoopers LLC. Study of pharmaceutical benefit management. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/cms_2001_4.pdf; Accessed 2/18, 2013.
11. Pharmacy Benefit Management Institute, LP. PBM market share. http://pbmi-com.web33.winsvr.net/PBMmarketshare2.asp; Accessed 9/29, 2014.
12. Motheral BR, Fairman KA. The use of claims databases for outcomes research: Rationale, challenges, and strategies. *Clin Ther*. 1997;19(2):346-366. doi: S0149-2918(97)80122-1 [pii].
13. Lauffenburger JC, Balasubramanian A, Farley JF, et al. Completeness of prescription information in US commercial claims databases. *Pharmacoepidemiol Drug Saf*. 2013;22(8):899-906. doi: 10.1002/pds.3458 [doi].
14. Gamble JM, Johnson JA, Majumdar SR, McAlister FA, Simpson SH, Eurich DT. Evaluating the introduction of a computerized prior-authorization system on the completeness of drug exposure data. *Pharmacoepidemiol Drug Saf*. 2013;22(5):551-555. doi: 10.1002/pds.3427 [doi].
15. Erickson SR, Coombs JH, Kirking DM, Azimi AR. Compliance from self-reported versus pharmacy claims data with metered-dose inhalers. *Ann Pharmacother*. 2001;35(9):997-1003.
16. Grymonpre RE, Didur CD, Montgomery PR, Sitar DS. Pill count, self-report, and pharmacy claims data to measure medication adherence in the elderly. *Ann Pharmacother*. 1998;32(7-8):749-754.
17. Quam L, Ellis LB, Venus P, Clouse J, Taylor CG, Leatherman S. Using claims data for epidemiologic research. the concordance of claims-based criteria with the medical record and patient survey for identifying a hypertensive population. *Med Care*. 1993;31(6):498-507.
18. McKenzie DA, Semradek J, McFarland BH, Mullooly JP, McCamant LE. The validity of medicaid pharmacy claims for estimating drug use among elderly nursing home residents: The oregon experience. *J Clin Epidemiol*. 2000;53(12):1248-1257.
19. King MA, Purdie DM, Roberts MS. Matching prescription claims with medication data for nursing home residents: Implications for prescriber feedback, drug utilisation studies and selection of prescription claims database. *J Clin Epidemiol*. 2001;54(2):202-209.

20. Kirking DM, Ammann MA, Harrington CA. Comparison of medical records and prescription claims files in documenting prescription medication therapy. *J Pharmacoepidemiol.* 1996;5:3-15.
21. Grymonpre R, Cheang M, Fraser M, Metge C, Sitar DS. Validity of a prescription claims database to estimate medication adherence in older persons. *Med Care*. 2006;44(5):471-477. doi: 10.1097/01.mlr.0000207817.32496.cb.
22. Mudd KE, Bollinger ME, Hsu VD, Manning A, Tsoukleris MG, Butz AM. Concordance of medicaid and pharmacy record data in inner-city children with asthma. *Contemp Clin Trials*. 2008;29(1):13-20. doi: 10.1016/j.cct.2007.05.002.
23. Pit SW, Byles JE, Cockburn J. Accuracy of telephone self-report of drug use in older people and agreement with pharmaceutical claims data. *Drugs Aging*. 2008;25(1):71-80.
24. Monster TB, Janssen WM, de Jong PE, de Jong-van den Berg LT, PREVEND Study Group Prevention of REnal and Vascular ENT Stage Disease. Pharmacy data in epidemiological studies: An easy to obtain and reliable tool. *Pharmacoepidemiol Drug Saf*. 2002;11(5):379-384. doi: 10.1002/pds.722.
25. Johnson RE, Vollmer WM. Comparing sources of drug data about the elderly. *J Am Geriatr Soc*. 1991;39(11):1079-1084.
26. Curtis JR, Westfall AO, Allison J, Freeman A, Kovac SH, Saag KG. Agreement and validity of pharmacy data versus self-report for use of osteoporosis medications among chronic glucocorticoid users. *Pharmacoepidemiol Drug Saf*. 2006;15(10):710-718. doi: 10.1002/pds.1226.
27. DosReis S, Zito JM, Speedie SM. Comparing medicaid prescription claims with clinic and pharmacy prescription profiles. *J Am Pharmaceut Assoc.* 1996(143):80.
28. Kozyrskyj AL, Mustard CA. Validation of an electronic, population-based prescription database. *Ann Pharmacother*. 1998;32(11):1152-1157.
29. Shrank WH, Choudhry NK, Fischer MA, et al. The epidemiology of prescriptions abandoned at the pharmacy. *Ann Intern Med*. 2010;153(10):633-640. doi: 10.7326/0003-4819-153-10-201011160-00005 [doi].
30. Martin BC, McMillian JA, Kotzan JA. Bias associated with missing out-of-plan prescription data for medicaid recipients: The whole truth. *J Res Pharmaceut Econ*. 1996(7):65 77.

Table 1. Demographic and Pharmacy Benefit Statistics for the Eligible Sample and Recipients with Their Pharmacy Profile Returned

	Eligible Sample, n=1,484		Recipients with a pharmacy profile returned, n=323		p-value**
	(n)	(%)	(n)	(%)	
Female	871	58.69%	195	60.37%	0.4902
Age (mean / s.d.)	46.6	(14.7)	46.7	(15.1)	0.8553
Elderly > 65 years	159	10.71%	38	11.76%	0.4884
Coinsurance*	246	16.58%	61	18.89%	0.6365
Two Tier Copay*	410	27.63%	77	23.84%	0.0851
Three Tier Copay*	643	43.33%	147	45.51%	0.3709
Deductible*	246	16.58%	65	20.12%	0.0526
Chain Pharmacy	1236	83.29%	265	82.04%	0.4997
Independent Pharmacy	248	16.71%	58	17.96%	NA
TOTAL	1484	100.00%	323	100.00%	

* members with that pharmacy benefit feature

** Chi-Square or t-test of difference between recipients with a pharmacy profile and those without a pharmacy profile

Table 2. Frequency of People by the number of prescriptions per person not captured on PBM claims

Number of Rxs Not on PBM Claims	Frequency of Persons	%	Number of Rxs Paid for Out of Pocket**	Frequency of Persons	%	Number of Rxs Paid for by Other 3rd Party***	Frequency of Persons	%
1	33	54.1%	1	24	57.1%	1	6	54.5%
2	5	8.2%	2	2	4.8%	2	2	18.2%
3	4	6.6%	3	7	16.7%	6	1	9.1%
4	3	4.9%	4	4	9.5%	8	1	9.1%
5	6	9.8%	5	3	7.1%	9	1	9.1%
6	1	1.6%	7	1	2.4%			
7	1	1.6%	10	1	2.4%			
8	2	3.3%						
9	1	1.6%						
10	2	3.3%						
13	1	1.6%						
15	1	1.6%						
24	1	1.6%						
TOTAL	61	100.0%		42	100.0%		11	100.0%

** Prescriptions where the source of payment could be determined from the pharmacy profile and was known to be paid for out of pocket

*** Prescriptions where the source of payment could be determined from the pharmacy profile and was known to be paid for by some other third party

*****source of payment could not be determined for 77 prescriptions records derived exclusively from the pharmacy profiles*

Table 3. Demographic and Pharmacy Benefit Features of Those With and Without Missing Prescription Records from PBM Claims

	At least One Missing Record from PBM Claims n= 61 mean / freq (s.d. / %)	No Missing Records from PBM Claims n=254 mean / freq (s.d. / %)	p-value	weighted*** p-value
Age	48.7 (14.3)	46.3 (15.4)	0.2616	0.4034
N Elderly (age >65)	9 (14.8%)	29 (11.4%)	0.4724	0.9945
N Female	37 (60.7%)	153 (60.2%)	0.9525	0.8581
Independent Pharmacy	15 (24.6%)	41 (16.1%)	0.1212	0.1318
Number of Rxs	16.4 (15.0)	7.8 (9.5)	<0.0001	<0.0001
Sum Paid for all Rxs	341.2 (491)	125.0 (162)	<0.0001	<0.0001
N with a Deductible	13 (21.3%)	49 (19.3%)	0.7216	0.6302
Family Deductible Amount $*	34.4 (179)	18.05 (111)	0.3658	0.5706
Member Deductible Amount $*	27.1 (92.7)	15.7 (59.0)	0.2370	0.3987
N with Coinsurance	11 (18.0%)	51 (20.1%)	0.7182	0.9687
N with Two Tier Copay	30 (49.2%)	133 (52.4%)	0.6552	0.6463
N with Three Tier Copay	31 (50.8%)	121 (47.6%)	0.6552	0.6463
Generic Copay Amount $ **	11.02 (4.8)	9.59 (4.8)	0.0609	0.0909
Preferred Brand Copay $ **	20.84 (9.9)	19.10 (8.1)	0.1967	0.2702
Non-Preferred Brand Copay $ **	22.12 (22.1)	19.92 (18.9)	0.4770	0.2548

* includes those with zero values when members do not have a deductible
** Based only on those without coinsurance (n=253) and includes those with zero values
*** sample weights derived to account for oversampling of persons with various pharmacy benefit features and significant differences are of the same direction as the unweighted analysis unless otherwise noted

Table 4. Multivariate Adjusted Odds Ratios of Factors Potentially Associated with Obtaining Prescriptions not on PBM Claims

	Unweighted n=253			Weighted = 253		
Parameter	Odds Ratio	95% CI		Odds Ratio	95% CI	
Age (yrs)	0.983	0.956	1.011	0.978	0.951	1.005
Gender (f=1)	0.814	0.400	1.654	0.809	0.407	1.611
Pharmacy Type (Chain=1)	0.915	0.392	2.135	0.775	0.353	1.704
Sum Prescriptions Filled	*1.084*	*1.047*	*1.123*	*1.081*	*1.051*	*1.113*
Deductible	1.003	0.433	2.322	1.070	0.333	3.435
Generic Copay Amount	*1.116*	*1.002*	*1.244*	1.120	0.989	1.270
Non-Preferred Brand Copay	0.996	0.978	1.015	1.003	0.983	1.024
Preferred Brand Copay	1.000	0.940	1.065	1.002	0.930	1.080

	Unweighted	Weighted
Model C-statistic	0.746	0.732
Prob. > Wald Chi-Square	0.0004	<0.0001

Table 5. Alternate Model with Coinsurance Status included and Copay Amounts Excluded

	Unweighted n=315			Weighted = 315		
Parameter	Odds Ratio	95% CI		Odds Ratio	95% CI	
Age (yrs)	0.993	0.971	1.016	0.980	0.954	1.006
Gender (f=1)	0.783	0.423	1.449	0.756	0.391	1.463
Pharmacy Type (Chain=1)	0.704	0.342	1.45	0.781	0.365	1.670
Sum Prescriptions Filled	*1.064*	*1.035*	*1.093*	*1.073*	*1.045*	*1.103*
Deductible	1.016	0.480	2.152	1.257	0.426	3.710
Three Tier Plan	1.038	0.525	2.053	0.978	1.110	2.154
Coinsurance	0.712	0.276	1.838	0.978	0.138	6.942

	Unweighted	Weighted
Model C-statistic	0.733	0.714
Prob. > Wald Chi-Square	0.0014	0.0001

Figure 1. Steps to obtain the study population and source of prescription records

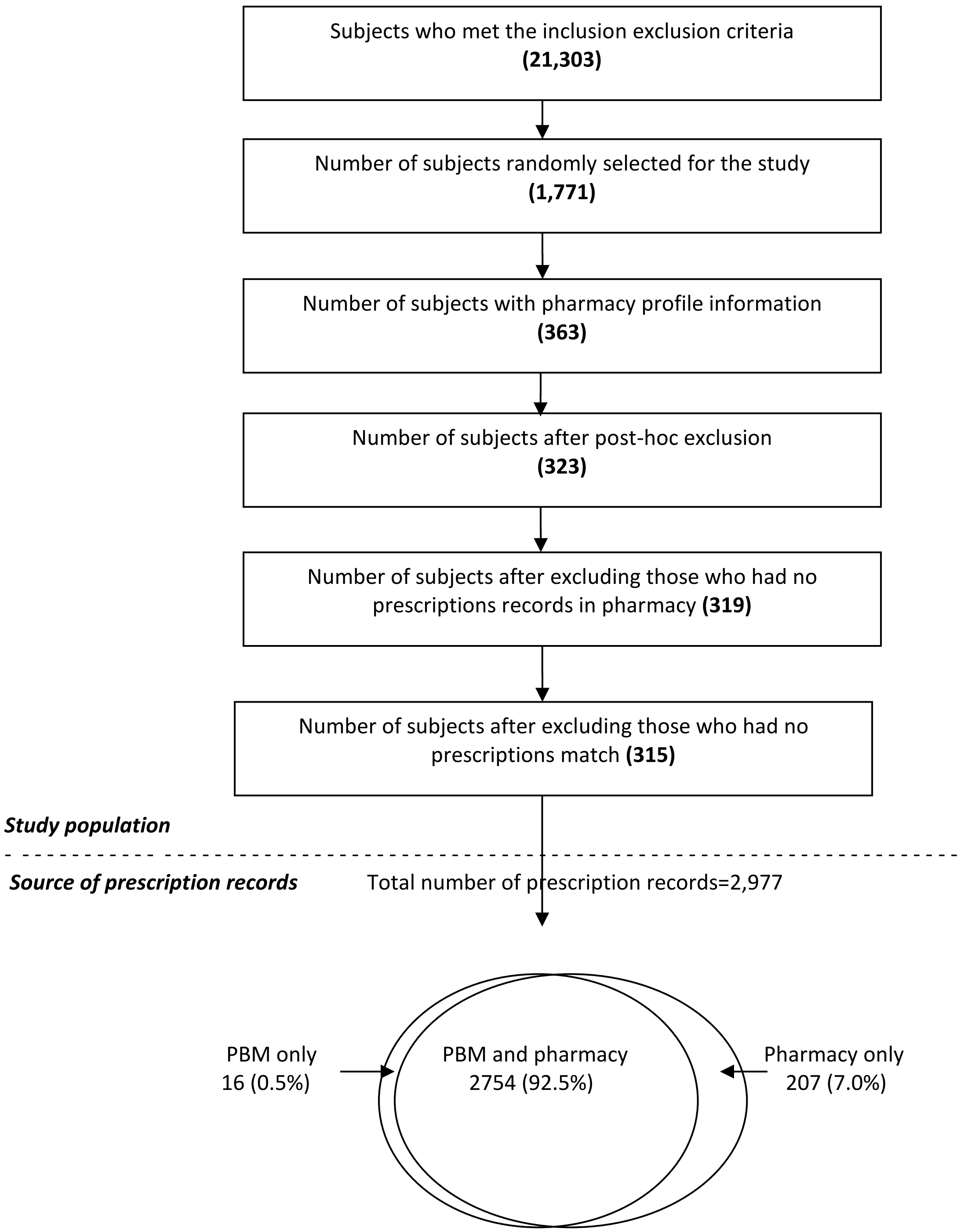

Figure 2. Source of Prescription Information for Most Common Therapeutic Classes